EPA Registration 89333-4

PROCESSING REQUEST

Reg # 89333-4 **Decision # 499556**

Description: New product registration Mancozeb 85 WP Manufacturing Use Concentrate

Electronic Label & Letter (see PPLS):	OR	**Non Electronic Label & Letter** (Scanning required):
X☐ Dated: 11/5/15		☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

X☐ New CSF(s) Dated: 01/21/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Maryam K. Muhammad

Division: RD

Phone: 703-347-0301 **Date: 11/24/2015**

PROCESSING REQUEST

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration

EPA Reg. Number:	Date of Issuance:
89333-4	11/5/15

Term of Issuance:
Conditional

Mancozeb 85 WP Manufacturing Use Concentrate

Name and Address of Registrant (include ZIP Code):

Don O'Shaughnessy
Agent for Agria Canada, Inc.
c/o D. O'Shaughnessy Consulting, Inc.
427 Hide Away Circle
Club Run, KY 42729

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Hope Johnson, Product Manager 21
Fungicide Branch, Registration Division (7505P)

Date: 11/5/15

EPA Form 8570-6

2. You are required to comply with the data requirements described in the DCI Order identified below:
    a. Mancozeb GDCI-014504-26952

    You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

4. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 89333-4."
    - Add appropriate Net Contents

5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/21/2015

If you have any questions, you may contact Maryam K. Muhammad at 703-347-0301 or via email at Muhammad.maryam@epa.gov.

Enclosure Product Chemistry Review of Mancozeb 85 WP Manufacturing Use Concentrate
Acute Toxicity Review of EPA File Symbol 89333-U (Mancozeb 85 WP Manufacturing Use Concentrate)

Mancozeb 85 WP Manufacturing Concentrate

A Fungicide for Formulating Use.

ACTIVE INGREDIENT:

Mancozeb (a coordination product of zinc ion and manganese ethylenebisdithiocarbamate) . . . . . 85 %

(in which the ingredients are:

Manganese++ 17.00%

Zinc++ 2.12%

Ethylenebisdithiocarbamate ion ($C_4H_6N_2S_4$) 65.88%

OTHER INGREDIENTS 15%

TOTAL: . . . . . 100.0 %

ACCEPTED

Nov 05, 2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg No. 89333-4

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

IF SWALLOWED: • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by the poison control center or doctor. • Do not give anything to an unconscious person.
IF ON SKIN OR CLOTHING: • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES: • Hold open and rinse slowly and gently with water or 15 to 20 minutes. • Remove contact lenses, if present, after the first minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **FOR CHEMICAL EMERGENCY: Spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300.**
This product contains mancozeb and ETU, chemicals known to the State of California to cause cancer. ETU is also known to the State of California to cause birth defects or other reproductive harm.

EPA Reg. No. 89333 - U EPA Est. No. 88475-BGR-1 Net Contents _____

Produced for: Agria Canada, Inc., 207 Bank. St.,Ste 412, Ottawa, ON Canada K2P 2N2
270-524-5633 Product of Bulgaria Batch No. _____

PHYSICAL AND CHEMICAL HAZARDS

Do not store near or use with oxidizing agents.

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed, inhaled or absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority.
For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Only for formulation into a fungicide for the following uses:
Field Corn, Corn grown for seed, Popcorn, Cotton (except foliar use), Peanuts, Sugarbeets, Wheat, Barley, Oats, Rye, Asparagus, Sweet corn, Cucumbers, Fennel, Melons (Cantaloupes, Casabas, Crenshaws, Honeydews, Watermelons), Onions (dry bulb and furrow drench), Potatoes, Potato tuber, Squash (summer), Tomatoes, Apples, Crabapples, Pears, Quince, Bananas, Cranberries, Grapes, Papayas, Walnuts, Almonds, Broccoli, Cabbage, Ginseng, Grapes, Lettuce, Papaya, Peppers, Sugar beet, Tropical Fruit (Mango, Star apple, Canistel, Mamey , Sapote , Sapodilla, White sapote, Ornamentals, Christmas trees; seed treatment of Barley, Corn, Cotton, Flax, Peanuts, Rice, Rye, Safflower, Sorghum, Tomato, Wheat, Triticale.

This product may be used to formulate products for specific use(s) not listed on this manufacturing use product label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

Manufacturers of products formulated as dusts must require closed systems for commercial seed and seedpiece treatment.

This product may not be used to manufacture end use products for use on golf courses.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container in a dry area. Keep away from sources of ignition, (e.g. sparks and open flame.) Close bag when not in use. Do not store in a manner where cross-contamination with other pesticides, fertilizers, food or feed could occur. If spilled during storage or handling, sweep up spillage and dispose of in accordance with the Pesticide Disposal Instructions listed below.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER HANDLING: Non-refillable container. No not reuse or refill this container. Completely empty bag into application equipment, then offer for recycling if available, or dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND CONDITIONS OF SALE

Agria Canada warrants only that the material contained herein conforms to the chemical description on the label and is reasonably fit for use therein described when used in accordance with the Directions for Use set forth in the label.

To the extent consistent with applicable law, any damage arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages, such as loss of profits or values or any other special or indirect damages. **Agria Canada** makes no other express or implied warranty including any other express or implied warranty of FITNESS or MERCHANTABILITY.

If you do not agree with or do not accept any of directions for use, the warranty disclaimers, or limitations on liability, do not use the product, and return it unopened to the Seller, and the purchase price will be refunded.

The sale of this product does not include a license under any patent owned by **Agria SA.**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

26/AUG/2015

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 89333-U

Name of Pesticide Product:	Mancozeb 85 WP Manufacturing Use Concentrate
EPA Reg. No.:	89333-U
DP Barcode:	D426766
Decision No.:	499556
Action Code:	R310
PC Code:	014504 (mancozeb)

From: Eugenia McAndrew, Biologist

Through: Masih Hashim, Ph.D., Toxicology Team Leader
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Maryam Muhammad, RM Team 21
Fungicide Branch
Registration Division (7505P)

Applicant: Agria Canada, Inc.
c/o D. O'Shaughnessy Consulting, Inc.

FORMULATION FROM LABEL:

Active Ingredient(s):		% by wt.
Mancozeb (a coordination of product zinc ion and manganese Ethylenebisdithiocarbamate) in which the ingredients are:		85
Manganese++	17.00	
Zinc++	2.12	
Ethylenebisdithiocarbamate ion	65.88	
Other Ingredient(s):		15
	Total:	100%

ACTION REQUESTED: The Risk Manager requests a review of acute toxicity data citations submitted to support the registration of EPA File Symbol 89333-U.

BACKGROUND: Agria Canada, Inc. has applied for registration of Mancozeb 85 WP Manufacturing Use Concentrate, EPA File Symbol 89333-U, containing 85% mancozeb. The submission includes a label, a basic CSF dated January 21, 2015, data matrix and company letter.

The registrant is not submitting product specific data to satisfy the acute toxicity data requirements. Instead, the registrant is citing acute toxicity data conducted on technical mancozeb. The data matrix lists the following MRIDs: acute oral (MRID 49580308), acute dermal (49580309), acute inhalation (MRID 49580310), primary eye irritation (MRID 49580311), primary dermal irritation (MRID 49580312) and dermal sensitization (49580313). These studies were reviewed in the memo for Mancozeb Technical, EPA Reg. No. 89333-3 (McAndrew; D428381; EPA Reg. No. 89333-3; 26/AUG/2015). Five of these studies were classified as acceptable; the dermal sensitization study was classified as unacceptable and therefore, will not support this registration.

COMMENTS AND RECOMMENDATIONS:

1. The cited acute oral, acute dermal, acute inhalation, primary eye irritation and primary skin irritation toxicity studies with MRIDs 495803-08 to -12 are acceptable to support the registration of 89333-U.

2. The cited dermal sensitization study (MRID 49580313) was classified as unacceptable. We will classify 89333-U as positive for dermal sensitization. The Reregistration Eligibility Document for Mancozeb, September 2005, page 12 states: "Although animal data indicate that mancozeb is not a skin sensitizer, incident reports in the public literature indicate that skin sensitization may occur in humans. The dermal sensitization study in animals is conducted on the manufacturing use product, whereas the reports of skin sensitization in humans are associated with end use products." Since the proposed product contains 15% of "other ingredients" the potential for sensitization exists. We note that the label submitted for 89333-U has the precautionary statement for dermal sensitization.

3. The acute toxicity profile for Mancozeb 85 WP Manufacturing Use Concentrate, EPA File Symbol 89333-U, is as follows:

acute oral toxicity	III	cited	MRID 49580308
acute dermal toxicity	III	cited	MRID 49580309
acute inhalation toxicity	IV	cited	MRID 49580310
primary eye irritation	III	cited	MRID 49580311
primary skin irritation	IV	cited	MRID 49580312
dermal sensitization	positive	cited	RED for Mancozeb

4. The proposed basic CSF submitted for 89333-U must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 089333-00004

PRODUCT NAME: Mancozeb 85 WP Manufacturing Use Concentrate

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. [Wear protective eyewear.]*

*[Protective eyewear may be specified, if appropriate.]

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment info

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

BARCODE No:426771;**DECISION No.:**499556;**FILE SYMBOL No.:** 89333-U;**FOOD Use: No;**
PRODUCT NAME: Mancozeb 85 WP Manufacturing Use Concentrate; PC Code 014504

DATE: **August 17, 2015**

SUBJECT: **Product Chemistry Review of Mancozeb 85 WP Manufacturing Use Concentrate**

FROM: **Akiva Abramovitch, Ph.D.**
CITAB / RD (7505P)

THROUGH: **Shyam Mathur, Ph.D.** 8/27/15
Product Chemistry Team Leader
CITAB /RD (7505P)

TO: **Maryam Muhammad/Hope Johnson, PM 21**
Fungicide and Herbicide Branch / Registration Division (7505P)

Company Name: Agria Canada
Formulation Type: MUP (WP)

INTRODUCTION:

The applicant has submitted an application for registration of a new manufacturing use product containing 85% Mancozeb as the active ingredient. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A and Group B data in MRID 495484-01 and -02. Also submitted the CSF of the basic formulation dated January 21, 2015 along with the product label. CITAB has been asked to determine the acceptability of the product chemistry data and the proposed basic CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredients: Mancozeb (85.0%),

2. Has the registrant claimed substantial similarity to a registered product?
[X] Yes; [] No; if yes give the registration number of the cited product. EPA Reg. No 89333-2

3. All the source materials for the active ingredients are derived from the registered sources:
[X] Yes; [ ] No.

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: [X] Yes; [ ] No.

5. Confidential Statement of Formula(s):
   [X] Basic CSF dated January 21, 2015
   [ ] Alternate CSF: None submitted

6. Product label

   a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).
   [X] Yes, if not, explain below:
   Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?
   [X] Yes; [ ] No; if not, explain below:

   Metallic equivalent: [ ] Yes [X] NA;
   Soluble arsenic: [ ] Yes [X] NA
   Isomeric ratios: [ ] Yes [X] NA
   Acid equivalent: [ ] Yes [X] NA; {name} Clopyralid acid equivalent = 2.1 %

   b. Health related sub statements: Product contains?

   Petroleum distillate at > 10%: [ ] Yes [X] No [ ] NA
   Methanol at > 4%: [ ] Yes [X] No [ ] NA
   Sodium nitrate/Sodium nitrite [ ] Yes [X] No [ ] NA

   c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
   [] Yes [X] No

   Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
   [ ] Yes, [ ] No, [X] NA, if not, explain below:

   d. Label requires an additional Storage and Disposal statement:
   [ ] Yes [X] No

BARCODE No:426771;**DECISION No.:**499556:**FILE SYMBOL No.:** 89333-U;**FOOD Use: No;**
PRODUCT NAME: Mancozeb 85 WP Manufacturing Use Concentrate; PC Code 014504

7. Group A: Product Chemistry Data
CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	495484-01
830.1600	Description of materials used to produce the product		X		A	495484-01
830.1650	Description of formulation process		X		A	495484-01
830.1670	Discussion on the formation of impurities		X		A	495484-01
830.1700	Preliminary analysis			X	NA	
	Certified limits (158.350)	Standard certified Limits	X		A	
		Proposed Limits				
830.1750		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	488688-03

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Yellow powder with a mild odor	A	495484-02
830.6314	Oxidation/ Reduction	The product did react with oxidizing or reducing agents	A	495484-02
830.6315	Flammability	Not flammable, above 100 C	A	495484-02
830.6316	Explodability	None	A	495484-02
830.7000	pH	7	A	495484-02
830.7100	Viscosity	Solid	A	495484-02
830.7300	Density (units)	18.73-24.97 Lb/Cu ft	A	495484-02

BARCODE No:426771;**DECISION No.:**499556;**FILE SYMBOL No.:** 89333-U;**FOOD Use: No;**
PRODUCT NAME: Mancozeb 85 WP Manufacturing Use Concentrate; PC Code 014504

CONCLUSIONS:

CITAB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed Basic CSF dated January 21, 2015 is acceptable.

2. The registrant satisfied the Group A and B data requirements with the exception of the storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) data studies which were not included with this submission and must be submitted when completed.

3. This product is not similar to the cited product having different percentages for the active ingredient and out of the certified limits listed on the CSFs

Muhammad, Maryam K.

From:	Don O'Shaughnessy <doctox@mac.com>
Sent:	Tuesday, July 28, 2015 12:13 PM
To:	Muhammad, Maryam K.
Subject:	Re: 89333-U; acute toxicity data submitted in support of this pending product
Attachments:	coverletmanco85June4-15-15.pdf; ATT00001.htm; matrixmanco85WP.pdf; ATT00002.htm; manco85toxwaiver2.pdf; ATT00003.htm; applic80WPacutetox7-7-15.pdf; ATT00004.htm; matrixmanco80WPjuly7-15.pdf; ATT00005.htm; matrixmancotechjuly7-15.pdf; ATT00006.htm; applicmancotechacutetox7-7-15.pdf; ATT00007.htm

Here is all the stuff they should have given you from the start. EPA seems to have a way with poor internal communication, so here is the long sad story:
- Way back in March, we submitted an *% WP product that is almost identical (a bit more mancozeb, a bit less [redacted]), and asked for a waiver for new tox, which was refused because, with no further thought, the basic rule said if the concentration of ai is higher you must kill some rats as a sacrifice to the fire gods. So round 2 was, OK, look, we have (but had not previously submitted because cite all is faster) the acute tox on the 80 WP and on the (92.3%) technical. If anything, the the data on the tech show it to be slightly *less* toxic (although no real difference). Mancozeb is just not acutely toxic. The logic is simple - the only possible change is if the *formulants* make it *more* toxic. The 85 WP has less of the same formulants, so logic dictates it is not any more toxic.
- OK so far, except (and I understand the reasoning) if we are submitting data generated using he 80 WP and the technical, we ought to submit them for those actual products. So therefore, the new application to add those MRIDs listed for th 85 WP on the tech and 80 WP matrices. All only one set of data, but now on multiple matrices.
- It may have been quicker, cheaper, and easier to just do the studies. But EU law is very strict and severe about that - NO NEW STUDIES ON VERTEBRATES IF ENOUGH DATA EXIST. It is actually a *felony,* with possible jail time. So we *have to* fight it.

Inert ingredient information may be entitled to confidential treatment

Muhammad, Maryam K.

From:	Johnson, Hope
Sent:	Monday, June 29, 2015 2:39 PM
To:	Don O'Shaughnessy; Don O'Shaughnessy
Cc:	Giles-Parker, Cynthia; Schaible, Stephen; Muhammad, Maryam K.
Subject:	89333-U; acute toxicity data submitted in support of this pending product

Dr. O'Shaughnessy,

The Agency has begun review of your resubmissions dated March 8, 2015, June 4, 2015 and June 9, 2015 for EPA File Symbol No. 89333-U; Decision Number 499556. You have submitted 2 sets of new 6-pack acute toxicity data not previously reviewed by the Agency, which support EPA Registration Numbers 89333-3 and 89333-2, and a bridging argument to satisfy the acute toxicity data requirements for –U based on these data.

We find it more appropriate that each new 6-pack of acute toxicity data be submitted as a R340 PRIA action under the corresponding Registration the data supports (either 89333-3 or 89333-2). The data you submitted could result in revised acute toxicity categories for 89333-3 and/or 89333-2 if the Agency review of this data results in categories that differ from the previously cited data for the respective products. Once the data is reviewed under each separate Registration Number, the Agency can then review the bridging argument for your pending R310 PRIA action (89333-U) and refer to the separate Agency reviews for -2 and -3.

Please note that the new studies, once reviewed, may require label changes regarding Precautionary or First Aid Statements for -2 or -3 if the acute toxicity categories differ from the previously cited data.

Please respond with your proposed course of action regarding 89333–U, -2 and -3 by Wednesday July 8, 2015.

Thank you,

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

Hope A. Johnson
Product Manager 21
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Fungicide Branch
Phone: 703-305-5410
Mail Code 7505P

doc
D. O'Shaughnessy Consulting, Inc.

June 9, 2015

Ms. Hope Johnson (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms.Johnson,
RE: 89333-U, Request for clarification, use of acute toxicity data for mancozeb 80% WP plus data from mancozeb technical to support mancozeb 85% WP: Response to email from M. K. Muhammad, June 4, 2015.

Thank you for your responses to this submission.

As indicated in the cover letter of March 11, 2015 (copy attached), EPA had previously rejected the *a priori* position of Agria Canada, Inc. that the toxicity of a mancozeb 85% WP product would not be different from that of a mancozeb 80% WP which contains the same formulants. Accordingly, Agria Canada submitted data new to US EPA (but which had been used to support EU registrations) to substantiate that claim of similarity. The use of these data was explained in a rational submitted at that same time (MRID 49580301, copy attached.)

By way of clarification, we note the following:

1. Acute toxicology requirements for Mancozeb 80 WP Manufacturing Concentrate (89333-2) were supported by citation of existing data (CITE ALL)
2. This same product is marketed in Europe, and was supported by acute toxicity data on that product.
3. Acute toxicity data submitted for 89333-U (MRIDs 49580302 - 49580307) were studies conducted by Agria S.A. (the parent company of Agria Canada) on Mancozeb 80 WP (89333-2), the exact same formulation as for Mancozeb 80 WP Manufacturing Concentrate. These studies, which were conducted to support registration in Europe, were not submitted to EPA previously to support 89333-2 because CITE-All submissions are processed more rapidly and at lower cost.
4. Acute toxicology requirements for Mancozeb Technical Fungicide (89333-3) were supported by citation of existing data (CITE ALL)
5. This same product is marketed in Europe, and was supported by acute toxicity data on that product,
6. Acute toxicology requirements for Mancozeb Technical Fungicide (89333-3) were supported by citation of existing data (CITE ALL)
7. Acute toxicity data submitted for 89333-U (MRIDs 49580308 - 49580312) were studies conducted by Agria S.A. (the parent company of Agria Canada) on Mancozeb Technical Fungicide (89333-3). These studies were not submitted to EPA previously to support 89333-3 because CITE-All submissions are processed more rapidly and at lower cost.

As detailed in MRID 49580301, the basic rationale is this:

1. Mancozeb technical is intrinsically of low toxicity.
2. It is theoretically possible that formulation off an end use product from a TGAI might increase toxicity (e.g. by enhanced absorption) but the data show that the formulants in Mancozeb 80 WP Manufacturing Concentrate do not in fact significantly change the toxicity between TGAI and formulated product.

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

3. These same formulants, in slightly different proportions are use to formulate the Mancozeb 85 WP Manufacturing Concentrate.
4. It is therefor reasonable to conclude that the intrinsically low toxicity of mancozeb technical will similarly not be increased relative to TGAI, nor to 80% WP.
5. It is a crime in the EU to conduct animal studies where sufficient data exist to determine safety of a product.
6. Agria believes that the above data an combination show that there is enough information already to conclude that the acute toxic effects of mancozeb TGAI, 80% WP, and *%% WP are significantly different, and label precautions for 80 WP and *% WP should be the same.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

ec Maryam K. Muhammad

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

doc
D. O'Shaughnessy Consulting, Inc.

Citation errors needs to be revised
-Maryam Muhammad

June4, 2015

Ms. Heather Garvie (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Garvie,
RE: 89333-U, Request for clarification, use of acute toxicity data for mancozeb 80% WP plus data from mancozeb technical to support mancozeb 85% WP: Response to email from M. K. Muhammad, June 4, 2015.

Thank you for your responses to this submission.

As indicated in the cover letter of March 11, 2015 (copy attached), EPA had previously rejected the *a priori* position of Agria Canada, Inc. that the toxicity of a mancozeb 85% WP product would not be different from that of a mancozeb 80% WP which contains the same formulants. Accordingly, Agria Canada submitted data new to US EPA (but which had been used to support EU registrations) to substantiate that claim of similarity. The use of these data was explained in a rational submitted at that same time (MRID 49580301, copy attached.)

By way of clarification, we note the following:

1. Acute toxicology requirements for Mancozeb 80 WP Manufacturing Concentrate (89333-2) were supported by citation of existing data (CITE ALL)
2. This same product is marketed in Europe, and was supported by acute toxicity data on that product.
3. Acute toxicity data submitted for 89333-U (MRIDs 49580302 - 49580307) were studies conducted by Agria S.A. (the parent company of Agria Canada) on Mancozeb 80 WP (89333-2), the exact same formulation as for Mancozeb 80 WP Manufacturing Concentrate. These studies, which were conducted to support registration in Europe, were not submitted to EPA previously to support 89333-3 because CITE-All submissions are processed more rapidly and at lower cost.
4. Acute toxicology requirements for Mancozeb Technical Fungicide (89333-3) were supported by citation of existing data (CITE ALL)
5. This same product is marketed in Europe, and was supported by acute toxicity data on that product,
6. Acute toxicology requirements for Mancozeb Technical Fungicide (89333-3) were supported by citation of existing data (CITE ALL)
7. Acute toxicity data submitted for 89333-U (MRIDs 49580308 - 49580312) were studies conducted by Agria S.A. (the parent company of Agria Canada) on Mancozeb Technical Fungicide (89333-3). These studies were not submitted to EPA previously to support 89333-3 because CITE-All submissions are processed more rapidly and at lower cost.

As detailed in MRID 49580301, the basic rationale is this:

1. Mancozeb technical is intrinsically of low toxicity.
2. It is theoretically possible that formulation off an end use product from a TGAI might increase toxicity (e.g. by enhanced absorption) but the data show that the formulants in Mancozeb 80 WP Manufacturing Concentrate do not in fact significantly change the toxicity between TGAI and formulated product.

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

3. These same formulants, in slightly different proportions are use to formulate the Mancozeb 85 WP Manufacturing Concentrate.
4. It is therefor reasonable to conclude that the intrinsically low toxicity of mancozeb technical will similarly not be increased relative to TGAI, nor to 80% WP.
5. It is a crime in the EU to conduct animal studies where sufficient data exist to determine safety of a product.
6. Agria believes that the above data an combination show that there is enough information already to conclude that the acute toxic effects of mancozeb TGAI, 80% WP, and *%% WP are significantly different, and label precautions for 80 WP and *% WP should be the same.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

ec Maryam K. Muhammad

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D426771; **FILE SYMBOL No.**: 89333-U (screen); **PRODUCT NAME**: Mancozeb 85 WP Manufacturing Use Concentrate; **DECISION No.**:499556; **PC Code(s)**: 014504; **ACTION CODE**: R310; **FOOD Use**: Yes

DATE OUT: April 24, 2015

SUBJECT: Completeness check screening for end use product "Mancozeb 85 WP Manufacturing Concentrate"

FROM: Shyam Mathur,
Product Chemistry Team Leader
CITAB/RD (7505P)

TO: Maryam Muhammad / Hope Johnson, RM 21
Fungicide Branch / RD (7505P)

Company Name: Agria Canada Incorporation
Formulation Type: Fungicide
Active Ingredient(s): Mancozeb (85.0%)
MRID No(s).: 49548401 & -02, cited 48993801, 48868803

CONCLUSION:

Deficiencies: No
(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: Required data submitted.

Group B: All required data submitted.

CSF: Basic CSF (dated 01-21-2015) submitted.

PRODUCT LABEL: Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 20, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

D. O'SHAUGHNESSY CONSULTING, INC.
AGRIA CANADA, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 11-MAR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-03, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

49580302

* Judging from the pagination of the study, pages____21, 22____ were omitted from the

submitted copy.

* This study is incomplete; data is missing from thefollowing page(s):____5____.

49580306

* Judging from the pagination of the study, pages____20, 21____ were omitted from the submitted copy.

* This study is incomplete; data is missing from thefollowing page(s):_____5_____.

49580311

* Judging from the pagination of the study, pages____20, 21_____ were omitted from the submitted copy.

49580313

* Judging from the pagination of the study, pages____19, 20_____ were omitted from the submitted copy.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 17, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-499556
EPA File Symbol or Registration Number: 89333-U
Product Name: Mancozeb 85 WP Manufacturing Use Concentrate
EPA Receipt Date: 28-Jan-2015
EPA Company Number: 89333
Company Name: AGRIA CANADA, INC.

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC.
AGRIA CANADA, INC.
C/O D. O'SHAUGHNESSY CONSULTING, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee **(REVISED)**

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);CHILD RESISTANT PACKAGING;

The fee for PRIA code R310 is $5,048, of which you have already paid $1,506. Please remit payment in the amount of $3,542 within 14 days to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

Pages 28-31: Access to FIFRA Registration Data is restricted under FIFRA 10 (G)

3|16

D. O'Shaughnessy Consulting, Inc.

March 11, 2015

Ms. Hope Johnson (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Johnson,
RE: Application to register Mancozeb 85 WP Manufacturing Concentrate on behalf of Agria Canada, Inc. (89333-X) **CORRECTED MARCH 11 - 15**

Enclosed is a DVD with a response to the email from Marianne Lewis of Feb. 24, 2015. (text attached:
We have conducted a Similarity Screen for the EPA Reg No 89333-U/Mancozeb 85 WP MUP registration package. In the application package you have claimed similarity to EPA Reg. No. 89333-2 and are doing a "cite all" for the acute toxicity study requirements. The CSFs from the subject product and the cited product were compared. The subject product contains, as you stated, 85% mancozeb and the cited product contains 80% mancozeb. EPA Reg. No. 89333-2 is not substantially similar to the subject product. You cannot cite data from a lower percentage product to satisfy the data requirements for a higher percentage product. Please cite another product that you feel is similar to your new product or cite a set of MRID's to fulfill the acute toxicity study requirements.
You now have ten business days to respond (by 3/10/15) or withdraw your application package – otherwise the rejection process with begin.

Agria believes that EPA *does* in fact have sufficient information to warrant the use of data on mancozeb technical + mancozeb 80% WP and so avoid the serious problem of additional animal use by a company resident in Europe. Never-the-less, we hereby provide a complete set of studies on both technical and 80% WP products to support the revised rationale included. Also included is a revised data matrix to include these data.

As you will understand from recent discussions, I hope these 10 business days take into account the 7 days during which Kentucky was in a declared State of Emergency due to extreme weather, during which time I was unable to access my office, nor reach any facility to send the included materials.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2
Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729

for

Agria Canada, Inc.

2. Regulatory Action in Support of Which This Package is Submitted

Application to register Mancozeb 85 WP Manufacturing Use Concentrate containing mancozeb

3. Transmittal Date

March8, 2015

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 14: Administrative materials (Cover letter, this Document, data matrix)

Volume 2 of 14 : Rationale to rely on acute toxicity data for 80% WP + mancozeb technical in support of 85% WP MRID 49580301

Volume 3 of 14: Acute oral toxicity, Mancozeb 80 WP MRID 49580302

Volume 4 of 14: Acute dermal toxicity, Mancozeb 80 WP MRID 49580303

Volume 5 of 14: Acute inhalation toxicity, Mancozeb 80 WP MRID 49580304

Volume 6 of 14: Dermal irritation, Mancozeb 80 WP MRID 49580305

Volume 7 of 14: Eye irritation, Mancozeb 80 WP MRID 49580306

Volume 8 of 14: Sensitization, Mancozeb 80 WP MRID 49580307

Volume 9 of 14: Acute oral toxicity, Mancozeb technical MRID 49580308

Volume 10 of 14: Acute dermal toxicity, Mancozeb technical MRID 49580309

Volume 11 of 14: Acute inhalation toxicity, Mancozeb technical MRID 49580310

Volume 12 of 14: Dermal irritation, Mancozeb technical MRID 49580312

Volume 13 of 14: Eye irritation, Mancozeb technical MRID 49580311

Volume 14 of 14: Sensitization, Mancozeb technical MRID 49580313

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM

Contact Information: tel. 270.524.5633 / cell 270-537-5139
fax 270.524.5634
email doctox@mac.com

D. O'Shaughnessy Consulting, Inc.

March 8, 2015

Citation errors needs to be revised
-Maryam Muhammad

Ms. Heather Garvie (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Garvie,
RE: 89333-U, Request for clarification, use of acute toxicity data for mancozeb 80% WP plus data from mancozeb technical to support mancozeb 85% WP: Response to email from M. K. Muhammad, June 4, 2015.

Thank you for your responses to this submission.

As indicated in the cover letter of March 11, 2015 (copy attached), EPA had previously rejected the *a priori* position of Agria Canada, Inc. that the toxicity of a mancozeb 85% WP product would not be different from that of a mancozeb 80% WP which contains the same formulants. Accordingly, Agria Canada submitted data new to US EPA (but which had been used to support EU registrations) to substantiate that claim of similarity. The use of these data was explained in a rational submitted at that same time (MRID 49580301, copy attached.)

By way of clarification, we note the following:

1. Acute toxicology requirements for Mancozeb 80 WP Manufacturing Concentrate (89333-2) were supported by citation of existing data (CITE ALL)
2. This same product is marketed in Europe, and was supported by acute toxicity data on that product.
3. Acute toxicity data submitted for 89333-U (MRIDs 49580302 - 49580307) were studies conducted by Agria S.A. (the parent company of Agria Canada) on Mancozeb 80 WP (89333-2), the exact same formulation as for Mancozeb 80 WP Manufacturing Concentrate. These studies, which were conducted to support registration in Europe, were not submitted to EPA previously to support 89333-3 because CITE-All submissions are processed more rapidly and at lower cost.
4. Acute toxicology requirements for Mancozeb Technical Fungicide (89333-3) were supported by citation of existing data (CITE ALL)
5. This same product is marketed in Europe, and was supported by acute toxicity data on that product,
6. Acute toxicology requirements for Mancozeb Technical Fungicide (89333-2) were supported by citation of existing data (CITE ALL)
7. Acute toxicity data submitted for 89333-U (MRIDs 49580308 - 49580312) were studies conducted by Agria S.A. (the parent company of Agria Canada) on Mancozeb Technical Fungicide (89333-2). These studies were not submitted to EPA previously to support 89333-2 because CITE-All submissions are processed more rapidly and at lower cost.

As detailed in MRID 49580301, the basic rationale is this:

1. Mancozeb technical is intrinsically of low toxicity.
2. It is theoretically possible that formulation off an end use product from a TGAI might increase toxicity (e.g. by enhanced absorption) but the data show that the formulants in Mancozeb 80 WP Manufacturing Concentrate do not in fact significantly change the toxicity between TGAI and formulated product.

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

3. These same formulants, in slightly different proportions are use to formulate the Mancozeb 85 WP Manufacturing Concentrate.
4. It is therefor reasonable to conclude that the intrinsically low toxicity of mancoeb technical will similarly not be increased relative to TGAI, nor to 80% WP.
5. It is a crime in the EU to conduct animal studies where sufficient data exist to determine safety of a product.
6. Agria believes that the above data an combination show that there is enough information already to conclude that the acute toxic effects of mancozeb TGAI, 80% WP, and *%% WP are significantly different, and label precautions for 80 WP and *% WP should be the same.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

ec Maryam K. Muhammad

427 Hide Away Circle, Cub Run, KY 42729 207 Bank St., Ste. 412, Ottawa, ON CANADA K2P 2N2

Phone 270-524-5633 cell 270-537-5139 email doctox@mac.com www.regtox.net

Lewis, Marianne

From: Lewis, Marianne
Sent: Friday, February 06, 2015 10:58 AM
To: 'doctoc@mac.com'
Subject: Similarity Clinic review for EPA Reg. No. 89333-U/Mancozeb 85 WP MUP

Mr. O'Shaughnessy,

We have conducted a Similarity Screen for the EPA Reg No 89333-U/Mancozeb 85 WP MUP registration package. In the application package you have claimed similarity to EPA Reg. No. 89333-2 and are doing a "cite all" for the acute toxicity study requirements. The CSFs from the subject product and the cited product were compared. The subject product contains, as you stated, 85% mancozeb and the cited product contains 80% mancozeb. EPA Reg. No. 89333-2 is not substantially similar to the subject product. You cannot cite data from a lower percentage product to satisfy the data requirements for a higher percentage product. Please cite another product that you feel is similar to your new product or cite a set of MRID's to fulfill the acute toxicity study requirements.

You have 10 business days to respond (by 2/20/15) or withdraw you application package – otherwise the rejection process will begin.

If you have any questions please contact me.

Marianne

Marianne Lewis
Biologist
IRB/RD
703 308-8043

Mr O'Shaughnessy called back 11:30 - said he never got email - there was a typo on his letter w/ the email address - so resent the 10 day letter - gave him to 3/10/15 to respond.

called - left voice mail 2/24/15 left message to call me back otherwise rejection

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 30, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-499556
EPA File Symbol or Registration Number: 89333-U
Product Name: Mancozeb 85 WP Manufacturing Use Concentrate
EPA Receipt Date: 28-Jan-2015
EPA Company Number: 89333
Company Name: AGRIA CANADA, INC.

DON O'SHAUGHNESSY, PH.D
D. O'SHAUGHNESSY CONSULTING, INC.
AGRIA CANADA, INC.
C/O D. O'SHAUGHNESSY CONSULTING, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300
NEW PRODUCT;OR SIMILAR COMBINATION PRODUCT (ALREADY REGISTERED) TO AN IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;REGISTERED SOURCE OF ACTIVE INGREDIENT;NO DATA REVIEW ON ACUTE TOXICITY, EFFICACY OR CRP - ONLY PRODUCT CHEMISTRY DATA;CITE-ALL DATA CITATION, OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA, OR APPLICANT SUBMITS SPECIFIC AUTHORIZATION LETTER FROM DATA OWNER;CATEGORY ALSO INCLUDES 100% RE-PACKAGE OF REGISTERED END-USE OR MANUFACTURING-USE PRODUCT THAT REQUIRES NO DATA SUBMISSION NOR DATA MATRIX;

The fee for action code R300 is $1,506. You have already paid $1,217. Please remit additional payment in the amount of **$289** to correct this underpayment to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 979074
St. Louis, MO 63197-9000

By Courier:
U.S. Bank
Government Lockbox 979074
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, MO 63197
Telephone: (314) 425-1818

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a partial waiver of the registration service fee if, for example, you qualify as a small business. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

By Courier:
Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 14 days, the Agency will presume that you no longer want to pursue this action. The Agency will then reject your application and issue an invoice for any applicable outstanding fees. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

Teresa Davis

Front End Processing Staff
Information Technology & Resources Management Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2015

D. O'SHAUGHNESSY CONSULTING, INC.
AGRIA CANADA, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 28-JAN-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

doc

D. O'Shaughnessy Consulting, Inc.

January 21, 2015

Ms. Hope Johnson (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Johnson,
RE: Application to register Mancozeb 85 WP Manufacturing Concentrate on behalf of Agria Canada, Inc. (89333-X)

Enclosed is a DVD with an e-submission to apply for registration of the subject product. As indicated in the attached documents, this is essentially similar to Mancozeb 80 WP MUC (89333-2), but with a slightly higher concentration of mancozeb. Accordingly we believe citation of the same acute toxicology data relied upon for registration of 89333-2 should apply to the subject product.

We note that the subject label updates the list of crops to correspond with the listing of crops on the Fortuna 74 WDG label (89333-1) that is presently pending at EPA. Appropriate offers-to-pay are listed in the data matrix.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

427 Hide Away Circle, Cub Run, KY 42729
Phone 270-524-5633 fax 270-524-5634 email doconslt@earthlink.net

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729

for

Agria Canada, Inc.

2. Regulatory Action in Support of Which This Package is Submitted

Application to register Mancozeb 85 WP Manufacturing Use Concentrate containing mancozeb

3. Transmittal Date

Jan. 21, 2015

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 4: Administrative materials (Cover letter, this Document, Application, data matrix, Certification with respect to citation of data, draft label, PRIA fee check.)

Volume 2 of 4: Manufacturing method + formation of impurities MRID 49548401

Volume 3 of 4: Physical / Chemical Properties MRID 49548402

Volume 4 of 4: Rationale to rely on acute toxicity data for 80% WP in support of 85% WP MRID 49548403

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM

Contact Information: tel. 270.524.5633 / cell 270-537-5139
fax 270.524.5634
email doctoc@mac.com

Fee for Service

{963484B~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 21

Receipt No. S-	963484
EPA File Symbol/Reg. No.	89333-U
Pin-Punch Date:	1/28/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: B660

Granted: R300

Amount Due: $ 1,506.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

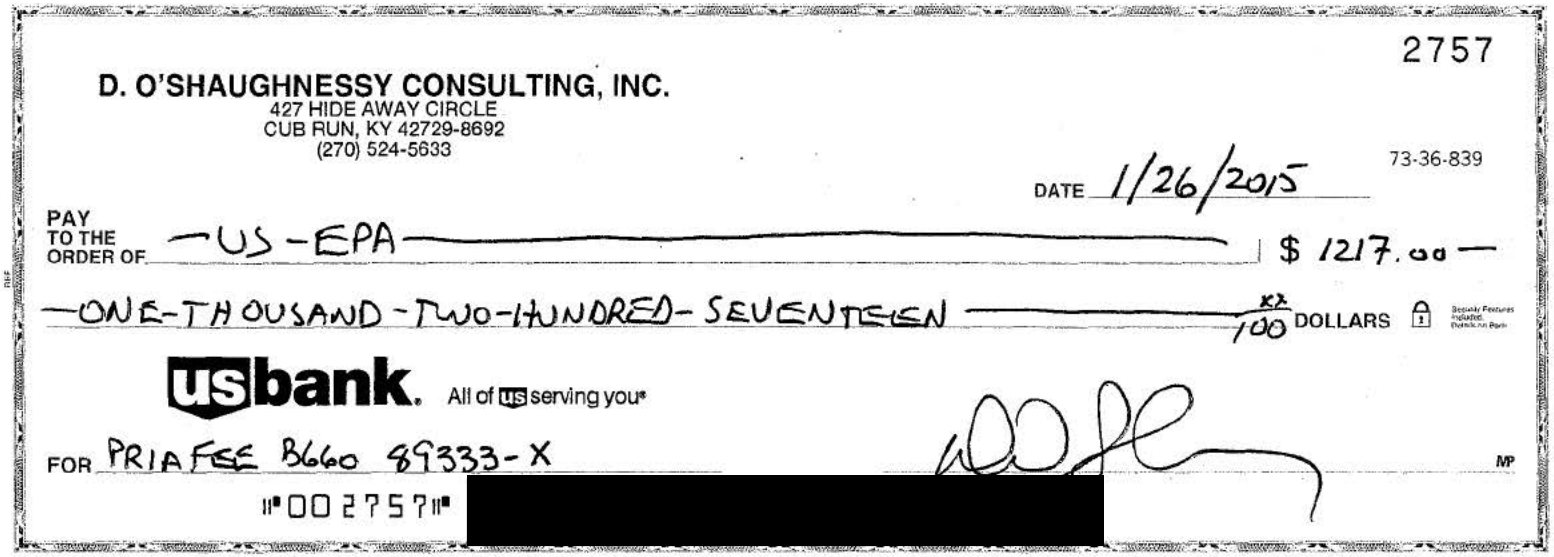
Reviewer: _____ Date: 1-30-15

Remarks:

- Similarity clinic

e-Submission

Commercial/financial information may be entitled to confidential treatment



2757

D. O'SHAUGHNESSY CONSULTING, INC.
427 HIDE AWAY CIRCLE
CUB RUN, KY 42729-8692
(270) 524-5633

73-36-839

DATE 1/26/2015

PAY TO THE ORDER OF —US-EPA— $ 1217.00

—ONE-THOUSAND-TWO-HUNDRED-SEVENTEEN— xx/100 DOLLARS

usbank. All of us serving you®

FOR PRIA FEE B660 89333-X

⑈002757⑈ [redacted]

MP

e-Submission

...lease read instructions on reverse before comp... form. Form Approved. ...R No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] ...gistration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 89333 - x

2. EPA Product Manager: Waller

3. Proposed Classification: [X] None [ ] Restricted

4. Company/Product (Name): Agria Canada / Mancozeb 85 WP Manufacturing Use Concentrate

PM# 21

5. Name and Address of Applicant *(Include ZIP Code)*
Agria Canada, Inc.,
133 Mavety St.,
Toronto, ON M6P 2L8 CANADA

[ ] *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. 89333-2
Product Name Mancozeb 80 WP Manufacturing Use Concentrate

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Application to register new product almost identical to 89333-2 (mancozeb 80%), but with 85% mancozeb

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[ ] Yes [X] No	[ ] Yes [X] No	[ ] Metal [ ] Plastic [ ] Glass [X] Paper [ ] Other (Specify) foil lined
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: [X] Label [ ] Container

4. Size(s) Retail Container: 30 lb, 50 lb

5. Location of Label Directions: [X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Don O'Shaughnessy	Agent	270-524-5633

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: 

3. Title: Agent

4. Typed Name: Don O'Shaughnessy

5. Date: Jan. 21, 2015

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

e-Submission

doc
D. O'Shaughnessy Consulting, Inc.

January 21, 2015

Ms. Hope Johnson (PM 21)
US EPA, RD (7504P)
Rm. S-4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202-4501

Dear Ms. Johnson,
RE: Application to register Mancozeb 85 WP Manufacturing Concentrate on behalf of Agria Canada, Inc. (89333-X)

Enclosed is a DVD with an e-submission to apply for registration of the subject product. As indicated in the attached documents, this is essentially similar to Mancozeb 80 WP MUC (89333-2), but with a slightly higher concentration of mancozeb. Accordingly we believe citation of the same acute toxicology data relied upon for registration of 89333-2 should apply to the subject product.

We note that the subject label updates the list of crops to correspond with the listing of crops on the Fortuna 74 WDG label (89333-1) that is presently pending at EPA. Appropriate offers-to-pay are listed in the data matrix.

As always, thank you for your attention to this so far, and if you require any further action, please contact me at the co-ordinates on this letterhead or at my cell # (270-537-5139).

Sincerely,

Don O'Shaughnessy, Ph.D., DABT

427 Hide Away Circle, Cub Run, KY 42729
Phone 270-524-5633 fax 270-524-5634 email doconslt@earthlink.net

e-Submission

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter

D. O'Shaughnessy Consulting, Inc., 427 Hide Away Circle, Cub Run, KY 42729

for

Agria Canada, Inc.

2. Regulatory Action in Support of Which This Package is Submitted

Application to register Mancozeb 85 WP Manufacturing Use Concentrate containing mancozeb

3. Transmittal Date

Jan. 21, 2015

4. List of Submitted Materials (e-submission on DVD)

Volume 1 of 4: Administrative materials (Cover letter, this Document, Application, data matrix, Certification with respect to citation of data, draft label, PRIA fee check.)

Volume 2 of 4: Manufacturing method + formation of impurities MRID 49548401

Volume 3 of 4: Physical / Chemical Properties MRID 49548402

Volume 4 of 4: Rationale to rely on acute toxicity data for 80% WP in support of 85% WP

Transmitted by: Don O'Shaughnessy, Ph.D., DABT, DABFM

Contact Information: tel. 270.524.5633 / cell 270-537-5139
fax 270.524.5634
email doctoc@mac.com

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 1-28-15

Experts In-Processing Signature: B.B. Date 1-30-15 Fee Paid: Yes ✓

Division management contacted on issues No _____ Yes _____ Date _____

EPA Reg. Number: 89333-U	EPA Receipt Date: 1-28-15

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)	X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) — yes: X; no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes: ; no:			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) — yes: X; no:			
	b) Cite-All (Fee category experts use)			
	c) Applicant owns all data (Fee category experts use)			
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**	X		
7	**Is the data package consistent with PR Notice 86-5**	X		
8	**Notice of Filing included with petitions**			X

9	**If applicable for conventional applications, reduced risk rationale**			X
10	**Required Data and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* Ineas approved for non-food use
* Submitted Studies PASSED PRN 11-3 Review
* Jacket PASSED

JJ 2/3/15

MRID: 495484

R 300 and 301

100% identical (repack): YES or (NO) (circle one)
{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	✓	
830.1600	Description of materials used to produce the product	✓	
830.1650	Description of formulation process	✓	
830.1670	Discussion on the formation of impurities	✓	
830.1700	Preliminary analysis	✓	
830.1750	Certified limits (158.345)	✓	
830.1800	Enforcement analytical method	✓	

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	✓	
830.6303	Physical State	✓	
830.6304	Odor	✓	
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓	
830.6315	Flammability	✓	
830.6316	Explodability	✓	
830.6317	Storage stability	✓	
830.6319	Miscibility	✓	
830.6320	Corrosion Characteristics	✓	
830.6321	Dielectric Breakdown voltage	✓	
830.7000	pH	✓	
830.7100	Viscosity	✓	
830.7300	Density	✓	

R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	✓	
870.1200	Acute Dermal (LD50)	✓	
870.1300	Acute Inhalation (LC50)	✓	
870.2400	Acute Eye Irritation	✓	
870.2500	Acute Dermal Irritation	✓	
870.2600	Dermal Sensitization	✓	

Efficacy - which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			not required
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			
810.3300	Treatments to Control Pests of Humans and Pets			
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			
810.3500	Premises Treatments			
810.3600	Structural Treatments			
810.3800	Methods for Efficacy Testing of Termite Baits			

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Agria Canada, Inc.. 207 Bank St., Suite 412, Ottawa, ON, CANADA K2P 2N2	89333-X
Active Ingredient(s) and/or representative test compound(s) mancozeb	Date Jan. 21, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) outdoor food, non-food	Product Name Mancozeb 85 WP Manufacturing Use Concentrate

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

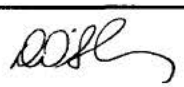
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	Jan. 21, 2015	Don O'Shaughnessy, Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Based on Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 03/08//2015			EPA Reg. No./File Symbol 89333-X		Page 1 of 6
Applicant's/Registrant's Name & Address Agria Canada Inc., 207 Bank. St. Suite 412, Ottawa ON Canada K2P 2N2			Product Mancozeb 85 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	(CSF) 49548400	Agria Canada, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	49548401	Agria Canada, Inc.	OWN	
830.1620	Description of Manufacturing Process	49548401	Agria Canada, Inc.	OWN	
830.1670	Discussion of Formation of Impurities	49548401	Agria Canada, Inc.	OWN	
830.1750	Certified Limits	49548400	Agria Canada, Inc.	OWN	
830.1800	Enforcement analytical method	48868803	Agromarketing Inc.	OWN	
830.6303	Physical State	49548402	Agria Canada, Inc.	OWN	
830.6304	Odor	49548402	Agria Canada, Inc.	OWN	
830.7300	Density	49548402	Agria Canada, Inc.	OWN	
830.6302	Color	49548402	Agria Canada, Inc.	OWN	
830.6315	Flammability	49548402	Agria Canada, Inc.	OWN	
830-6314	Oxidation / reduction	49548402	Agria Canada, Inc.	OWN	
830.6317 / 6320	Storage Stability / corrosion characteristics	48868803	Agria Canada, Inc.	OWN	
830.1800	Enforcement analytical method (additional)	48993801	Agria Canada, Inc.	OWN	
Signature			Name and Title Don O'Shaughnessy, Agent		Date 03/08//2015

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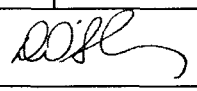
DATA MATRIX

Date 03/08//2015			EPA Reg. No./File Symbol 89333-X		Page 2 of 6
Applicant's/Registrant's Name & Address Agria Canada Inc., 207 Bank. St. Suite 412, Ottawa ON Canada K2P 2N2			Product Mancozeb 85 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	acute oral toxicicty	49580302	Agria Canada, Inc.	OWN	
870.1200	acute dermal toxicity	49580303	Agria Canada, Inc.	OWN	
870.1300	acute inhalation toxicity	49580304	Agria Canada, Inc.	OWN	
870.2400	acute eye irritation	49580306	Agria Canada, Inc.	OWN	
870.2500	acute dermal irritation	49580305	Agria Canada, Inc.	OWN	
870.2600	sensitization	49580307	Agria Canada, Inc.	OWN	
860.1500	magnitude of residue in walnuts	48645401	United Phosphorus, Inc.	PAY	
all other product-specific data		cite all		PAY	
NA	rationale for use of 80 WP data for 85% WP	49580301	Agria Canada, Inc.	OWN	
Signature			Name and Title Don O'Shaughnessy, Agent		Date 03/08//2015

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DATA MATRIX

Date 03/08//2015			EPA Reg. No./File Symbol 89333-X		Page 3 of 6
Applicant's/Registrant's Name & Address Agria Canada Inc., 207 Bank. St. Suite 412, Ottawa ON Canada K2P 2N2			Product Mancozeb 85 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	(CSF) 48449100	Agromarketing Company, Inc.	OWN	2
830.1600	Description of Materials Used to Produce the Product	48449101	Agromarketing Company, Inc.	OWN	2
830.1620	Description of Manufacturing Process	48449101	Agromarketing Company, Inc.	OWN	2
830.1670	Discussion of Formation of Impurities	48449101	Agromarketing Company, Inc.	OWN	2
830.1750	Certified Limits	48229200	Agromarketing Company, Inc.	OWN	2
830.1800	Enforcement analytical method	48449102	Agromarketing Company, Inc.	OWN	2
830.6303	Physical State	48449103	Agromarketing Company, Inc.	OWN	2
830.6304	Odor	48449103	Agromarketing Company, Inc.	OWN	2
830.6317 / 6320	Storage Stability / corrosion characteristics	489922501	Agromarketing Company, Inc.	OWN	2
830.7300	Density	48449103	Agromarketing Company, Inc.	OWN	2
830.6302	Color	48449103	Agromarketing Company, Inc.	OWN	2
830.7000	pH	48449103	Agromarketing Company, Inc.	OWN	2
830.7200	Melting point	48449103	Agromarketing Company, Inc.	OWN	2
830.7220	Boiling point	48449103	Agromarketing Company, Inc.	OWN	2
830.6315	Flammability	48449103	Agromarketing Company, Inc.	OWN	2
Signature			Name and Title Don O'Shaughnessy, Agent		Date 03/08//2015

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Date 03/08//2015			EPA Reg. No./File Symbol 89333-X		Page 4 of 6
Applicant's/Registrant's Name & Address Agria Canada Inc., 207 Bank. St. Suite 412, Ottawa ON Canada K2P 2N2			Product Mancozeb 85 WP Manufacturing Concentrate		
Ingredients mancozeb					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosivity	48449103	Agria Canada, Inc..	OWN	
830.6313	Stability to normal and elevated temperatures/.metal/	cite all	cite all	PAY	1
830.1700	Preliminary Analysis	48449102	Agria Canada, Inc...	OWN	
870.1100	acute oral toxicicty	49580308	Agria Canada, Inc.	OWN	
870.1200	acute dermal toxicity	49580309	Agria Canada, Inc.	OWN	
870.1300	acute inhalation toxicity	49580310	Agria Canada, Inc.	OWN	
870.2400	acute eye irritation	49580311	Agria Canada, Inc.	OWN	
870.2500	acute dermal irritation	49580312	Agria Canada, Inc.	OWN	
870.2600	sensitization	49580313	Agria Canada, Inc.	OWN	
all other generic data		cite-all		PAY	1
Signature			Name and Title Don O'Shaughnessy, Agent		Date 03/08//2015

Pages 57-58 - *Confidential Statements of Formula may be entitled to confidential treatment*